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Total Number of Pages in This Submission

8

Application Number

10/528,463

Filing Date

March 31, 2005

First Named Inventor

Chantal GUILLEMETTE et al.

Art Unit

1634

Examiner Name

Amanda Marie Shaw

Attorney Docket Number

6013-118US

ENCLOSURES (Check all that apply)

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Fee Transmittal Form

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Fee Attached

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Amendment/Reply

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Affidavits/declaration(s)

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Extension of Time Request

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Express Abandonment Request

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Information Disclosure Statement

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Certified Copy of Priority Document(s)

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Reply to Missing Parts/
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Proprietary Information

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Remarks

Number of pages does not include 61 references

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Firm Name

Ogilvy Renault, LLP

Signature

Printed name

Valérie Carrier

Date

July 7, 2006

Reg. No.

56,011

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File No. 6013-118US

Québec, Canada

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Chantal Guillemette et al.
Serial No. : 10/528,463
Filing Date : March 21, 2005
Art Unit : 1634
Title : METHOD FOR DETERMINING PREDISPOSITION TO
A PHYSIOLOGICAL REACTION IN A PATIENT

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. § 1.97

NO FEE

Commissioner for Patents
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Alexandria, VA 22313-1450

Sir:

Submitted herewith on a PTO/SB/08A/B form is a listing of the documents known to applicant in order to comply with applicant's duty of disclosure pursuant to 37 C.F.R. § 1.56.

The submission of any document which is not a statutory bar is not intended as an admission that such document constitutes prior art against the claims of the present application. Applicant does not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a prima facie prior art reference against the claims of the present application.

Statement of Relevancy

The listed document is being submitted either in compliance with 37 C.F.R. §1.97(b), within three (3) months of the filing date of a national application or of the date of entry of the national stage in an international application, or before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under §1.114; or pursuant to 37 C.F.R. §1.97(e)(1), within three (3) months from the date of an office action or of a search report issued in a foreign counterpart application citing each of the documents contained in the present statement; or pursuant to 37 C.F.R. §1.97(e)(2), within three (3) months from the first knowledge of each submitted document by any individual designated in C.F.R. §1.56(c), when each such document was not cited in a communication from a foreign patent office in a counterpart foreign application.

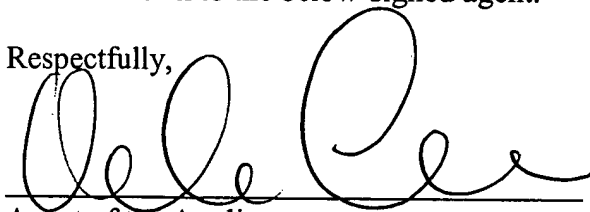
In the case of submission under 37 C.F.R. §1.97(e)(1) and (2), the undersigned Attorney/Agent of Record hereby certifies that the enclosed list of references is hereby submitted within three months (1) from the issuance of the foreign action or search report, or (2) from said first knowledge, respectively.

The Examiner is kindly requested to consider these references during the examination of the above-identified application, making the references of record, and to return an initialed copy of the PTO/SB/08A/B Form to the below-signed agent.

July 7, 2006

Date

Respectfully,

A handwritten signature in black ink, appearing to read 'Valérie Carrier', written over a horizontal line.

Agent of the Applicant

Valérie Carrier, Reg. No. 56,011

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Substitute for form 1449A and B/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	10/528,463
		Filing Date	March 21, 2005
		First Named Inventor	Chantal Guillemette
		Art Unit	1634
		Examiner Name	Amanda Marie Shaw
Sheet 1 of 5	Attorney Docket Number	6013-118US	

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
		Number – Kind Code ² (if known)			
		US 6,395,481 B1	05/28/2002	Di Rienzo et al.	
		US 2002016293 A1	02/07/2002	Ratain Mark J et al.	
		US 02/0115097 A1	08/22/2002	Rienzo et al.	
		US 2002/0061518 A1	05/23/2002	Penny et al.	
		US 6,528,260 B1	03/04/2003	Blumenfeld et al.	
		US 5589504	12/31/1996	Dannenberg et al.	

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant Of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
		Country Code3 – Number4 – Kind Code5 (if known)			
		WO 02/48400 A	06/20/2002	Ando Yu-Uichi et al.	
		EP 1352970	10/15/2003	Hasegawa et al.	
		WO 01/79230	10/25/2001	Chew et al.	
		WO 00/06776	02/10/2000	Galvin et al.	
		WO 99/57322	11/11/1999	Penny et al.	
		WO 02/053770	07/11/2002	Manns et al.	
		JP 02/085066	03/26/1990	Yamamoto	
		WO 02/06523	01/24/2002	Acuna et al.	
		WO 97/32042	09/04/1997	Burchell, Brian	
		WO 2004/027088 A3	04/01/2004	Guillemette, Chantal	
		WO 2002/18554	03/07/2002	Wei et al.	
		WO 96/01127	01/18/1996	Ratain M. et al.	
		WO 01/80896	11/01/2001	Ratain, M. et al.	
		WO 03/013536	02/20/2003	Heinrich et al.	
		WO92/12987	08/06/1992	Owens et al.	

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		DOUGLAS A.P. et al., 1978, "Paracetamol (acetaminophen) kinetics in patients with Gilbert's syndrome" Europe J Clin Pharmacol, 13:209-212	
		BRODER S. et al., 2002, "The human genome" Pharmacogenomics: The Search for Individual Therapies, pages 292-295	

Examiner Signature		Date Considered	
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*EXAMINER; Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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				Examiner Name	Amanda Marie Shaw
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		WOOLLEY A.T. et al., 2000, « Direct haplotyping of kilobase-size DNA using carbon nanotube probes», Nature Biotechnology, 18: 760-763	
		MACKLON A.F. et al., 1979, "Gilbert's Syndrome and Drug Metabolism", Clinical Pharmacokinetics, 4 :223-232	
		ANDO Y. et al., 2002, "Polymorphisms of UDP-Glucuronosyltransferase and Pharmacokinetics of Irinotecan", Therapeutic Drug Monitoring, 24: 111-116	
		ANDO Y. et al., 2000, "Polymorphisms of UDP-Glucuronosyltransferase Gene and Irinotecan Toxicity: A Pharmacogenetic Analysis", Cancer Research, 60: 6921-6926	
		ANDO Y. et al., 1998, "UGT1A1 genotypes and glucuronidation of SN-38, the active metabolite of irinotecan", Annals of Oncology, 9: 845-847	
		VOGEL A. et al., 2001, "Genetic Link of Hepatocellular Carcinoma with Polymorphisms of the UDP-Glucuronosyltransferase UGT147 Gene", Gastroenterology, 121: 1136-1144	
		BEAULIEU M. et al., 1996, "Isolation and Characterization of a Novel cDNA Encoding a Human UDP-Glucuronosyltransferase Active on C ₁₉ Steroids", The Journal of Biological Chemistry, 271: 22855-22862	
		BOSMA P. et al., 1994, "Presence of an additional TA in the TATAA box of B-UGT ₁ correlates with Gilbert syndrome", Hepatology, 20:680	
		ALBERT C. et al., 1999, "The Monkey and Human Uridine Diphosphate-Glucuronosyltransferase UGT1A9, Expressed in Steroid Target Tissues, Are Estrogen-Conjugating Enzymes", Endocrinology, 140: 3292-3302	
		KIHARA C. et al., 2001, "Prediction of Sensitivity of Esophageal Tumors to Adjuvant Chemotherapy by cDNA Microarray Analysis of Gene-Expression Profiles", Cancer Research, 61:6474-6479	
		CIOTTI M. et al., 1997, "Genetic Defects at the UGT1 Locus Associated With Crigler-Najjar Type I Disease, Including a Prenatal Diagnosis", American Journal of Medical Genetics, 68:173-178	
		FAUCHER M. et al., 2002, "Founder TIGR/myocilin mutations for glaucoma in the Québec population", Human Molecular Genetics, 11:2077-2090	

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		GAGNÉ J.-F. et al. "Common Human UGT1A Polymorphisms and the Altered Metabolism of Irinotecan Active Metabolite 7-Ethyl-10-hydroxycamptothecin", Molecular Pharmacology, 62: 608-617	
		GONG Q.-H. et al., 2001, "Thirteen UDPglucuronosyltransferase genes are encoded at the human UGT1 gene complex locus", Pharmacogenetics, 11:357-368	
		GUILLEMETTE C. et al., 2000, "Structural Heterogeneity at the UDP-Glucuronosyltransferase 1 locus: functional consequences of three novel missense mutations in the human UGT1A7 gene", Pharmacogenetics, 10: 629-644	
		GUILLEMETTE C. et al., 2001, "Association of Genetic Polymorphisms in UGT1A1 with Breast Cancer and Plasma Hormone Levels", Cancer Epidemiology, Biomarkers & Prevention, 10: 711-714	
		ZEMBUTSU H. et al., 2002, "Genome-wide cDNA Microarray Screening to Correlate Gene Expression Profiles with Sensitivity of 85 Human Cancer Xenografts to Anticancer Drugs", Cancer Research, 62:518-527	
		OWENS I.S. et al., 1995, « Gene structure at the human UGT1 locus creates diversity in isozyme structure, substrate specificity and regulation", Progress in Nucleic Acid Research and Molecular Biology, 51:305-338	
		INNOCENTI F. et al., 2001, "Pharmacogenetics of Anticancer Agents: Lessons from Amonafide and Irinotecan", Drug Metabolism and Disposition, 29:596-600	
		VENTER J.C. et al., 2001 "The sequence of the human genome", Science, 291:1304-1351	
		RAMIREZ J. et al., 2002, "In Vitro Characterization of Hepatic Flavopiridol Metabolism using Human Liver Microsomes and Recombinant UGT Enzymes", Pharmaceutical Research, 19: 588-594	
		MCCARTHY J.J., 2002, "Turning SNPs into useful markers of drug response" Pharmacogenomics : The search for individual therapies, pages 35-55	
		RITTER J.K. et al., 1992, "A Novel Complex Locus UGT1 Encodes Human Bilirubin, Phenol, and Other UDP-Glucuronosyltransferase Isozymes with Identical Carboxyl Termini", The Journal of Biological Chemistry 267: 3257-3261	
		KUHN J.G., 1998, "Pharmacology of Irinotecan", Oncology, 12 :39-42	

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Sheet	4	of	5

		IYER L. et al., 2002, "UGT1A1*28 polymorphism as a determinant of irinotecan disposition and toxicity", The Pharmacogenomics Journal, 2: 43-47	
		IYER L. et al., 1998, "Genetic predisposition to the metabolism of irinotecan (CPT-11): Role of Uridine Diphosphate Glucuronosyltransferase Isoform 1A1 in the Glucuronidation of its Active Metabolite (SN-38) in Human Liver Microsomes", Journal of Clinical Investigation, 101:847-854	
		SALTZ L.B. et al., 2000, « Irinotecan plus fluorouracil and leucovorin for metastatic colorectal cancer", The New England Journal of Medicine, 343 :905-914	
		MACKENZIE P.I., 2000, "Identification of Uridine Diphosphate glucuronosyltransferases involved in the metabolism and clearance of mycophenolic acid", Therapeutic Drug Monitoring, 22: 10-13	
		ANDO M. et al., 2002, "Genetic Polymorphisms of the UDP-glucuronosyltransferase 1A7 Gene and Irinotecan Toxicity in Japanese Cancer Patients", Japanese Journal of Cancer Research, 93: 591-597	
		MONAGHAN G. et al., 1996, "Genetic variation in bilirubin UDP-glucuronosyltransferase gene promoter and Gilbert's syndrome", Lancet, 347:578-581	
		CARULLI N. et al., 1976, "Alteration of drug metabolism in Gilbert's syndrome", Gut, 17 :581-587	
		MACKENZIE P.I. et al., 1997, "The UDP glycosyltransferase gene superfamily: recommended nomenclature update based on evolutionary divergence" Pharmacogenetics, 7:255-269	
		BOSMA P.J. et al., 1994, "Bilirubin UDP-glucuronosyltransferase 1 Is the Only Relevant Bilirubin Glucuronidating Isoform in Man", The Journal of Biological Chemistry, 269: 17960-17964	
		BOSMA P.J. et al., 1995, "The genetic basis of the reduced expression of bilirubin UDP-glucuronosyltransferase 1 in Gilbert's syndrome", The New England Journal of Medicine, 333: 1171-1175	
		HERMAN R.J. et al., 1994, "Disposition of Lorazepam in Gilbert's Syndrome: Effects of Fasting, Feeding, and Enterohepatic Circulation.", Journal of Clinical Pharmacology, 34:978-984	
		MEECH R. and Mackenzie P.I., 1997, "Structure and function of uridine diphosphate glucuronosyltransferases", Clinical and experimental pharmacology and physiology, 24: 907-915	

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		MEECH R. and Mackenzie P.I., 1997, «UDP-Glucuronosyltransferase, the Role of the Amino Terminus in Dimerization», The Journal of Biological Chemistry, 272: 26913-26917	
		BRODER S. et al., 2002, "The human genome" Pharmacogenomics: The Search for Individual Therapies, pages 9-34	
		DAN S. et al., 2002, "An Integrated Database of Chemosensitivity to 55 Anticancer Drugs and Gene Expression Profiles of 39 Human Cancer Cell Lines", Cancer Research, 62:1139-1147	
		SIMONEN R.L. et al., 2002, "Familial aggregation of physical activity levels in the Québec family study", Medicine and Science in Sports and Exercise, 34:1137-1142	
		DE MORAIS S.M.F. et al., 1992, "Decreased Glucuronidation and Increased Bioactivation of Acetaminophen in Gilbert's Syndrome », Gastroenterology; 102 :577-586	
		TUKEY R.H. et al., 2000, "Human UDP-Glucuronosyltransferases : Metabolism, Expression, and Disease" Annual Review of Pharmacology and Toxicology, 40: 581-616	
		WASSERMAN E. et al., 1997, « Severe CPT-11 toxicity in patients with Gilbert's syndrome : Two case reports », Annals of Oncology, 8 :1049-1051	
		DUTTON G.J., 1980, "Glucuronidation of Drugs and Other Compounds; Part I: Glucuronidation, glucuronides, and Studies on UDPGlucuronyltransferase In Vitro", CRC Press, Boca Raton, FL, pages 3-21	

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